CTMS Adverse Events Reporting SIG Teleconference
Meeting Minutes

Meeting Date	Friday, October 15, 2004
	3:00 – 4:00 PM EDT

Attendees:	
	Working group coordinator: Scott Finley (Booz Allen Hamilton)
	Harshawardhan Bal (Booz Allen Hamilton)
	Participants:

Name	Email	Center
Joyce Niland (SIG lead)	jniland@coh.org	City of Hope
Amy Cox	acox@coh.org	City of Hope
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Harshawardhan Bal	Bal_harshawrdhan@hab.com	BAH

Agenda	
	I. Review of Minutes: October 1, 2004
	II. Review of DCP SAE Process – CCOP
	Amy Cox (City of Hope)
	III. Update on NCI's Central IRB
	Amy Cox
	IV. Update on AdEERS and CDUS Processes
	V. Review of Updated Survey Results
	(Includes a new and updated survey, as well as comments from
	the University of Pittsburgh, previously omitted in error.)

General discussion points raised by participants:	VI. caBIG CTMS Face-to-Face Meeting: November 16-17, 2004 Please email Jennifer Neat (jneat@coh.org) to indicate your attendance. For registration purposes, please include your institution and contact information. VII. Transitioning Responsibility of Meeting Minutes Identify designated AE SIG participant VIII. Next Teleconference November 5, 2004
	Meeting minutes for October 1, 2004, accepted without amendments. Minutes by Robert Morrell, WFU. Amy Cox reviewed a diagram of DCP SAE/CCOP handling collection of AE events. There was a general discussion about the overlap/separation between CTEP and DCP procedures. The diagram's scope was limited to grade 4 and 5 SAEs. Oracle Clinical would handle those less than grade 4, though some might be re-graded up and then enter the diagram. Amy also discussed NCI's Central IRB project. She is waiting for a reply to a query from the NCI, and is in the process of analyzing data from the project's website. Scott suggested that he be cc'd on any queries to the NCI to facilitate a quicker response. Adeers and CDUS: The overlap between the various SIGs was discussed particularly with reference to dealing with vocabularies. It was pointed out that CTEP has already submitted a large portion of AE CDEs in caDSR, causing some participants to salivate audibly. DCP has a similar set of CDEs, and most, but not all of them, match up without any problems. An excel version of the file will be distributed to the group, with those 50+ codes marked where some resolution might be needed. A letter from Kim Kingler was mentioned, which dealt with the CDE process. In general, it was felt that we need to begin establishing reconciliation processes, but that we need to prioritize those CDEs that are exclusively or primarily in the SIG, then work up the chain. Amy Cox reviewed the updated survey results. An offline discussion is planned to bring in one remaining survey and to decide what other topics, if any, are needed. The CTMS face-to-face meeting was discussed, and it was decided to keep the Nov. 5th teleconference, but to cancel Nov. 19th. The group decided to rotate minute-taking responsibility for the SIG, causing the minute-taker to cheer loudly, fortunately his phone was on mute.

Action items:	Continue efforts to engage dialogue with NCI regarding NCI's CRIB (Amy Cox).
	Distribution of DCP CDEs to AE SIG participants.
	Coordinate an offline discussion to bring in one remaining response to the CTMS-CDUS survey request and to decide what other topics, if any, are needed.
	Rotate responsibility for taking and preparing minutes. Sorena Nadaf will take minutes for the teleconference scheduled for November 5, 2004.